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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,808	03/15/2000	Athanasius A Anagnostou	5218-39C	9764

20792 7590 07/02/2003

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/02/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/525,808	ANAGNOSTOU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 21 April 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 16-22 and 30-39 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 16,30-36 and 38 is/are rejected.

7) Claim(s) 17-22,37 and 39 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

1. The amendment filed 4/21/2003 (paper no. 15) is acknowledged and entered into the record. Accordingly, claims 30-39 are newly added.
2. Therefore, claims 16-22, and 30-39 are examined on the record.

#### ***Claim Rejection Withdrawn - 35 USC § 112, 2<sup>nd</sup> paragraph***

3. The rejection of claims 16-22 under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn in view of the arguments provided by the applicant.

#### ***Claim Rejections Withdrawn - 35 USC § 112, 1<sup>st</sup> paragraph***

4. The rejection of claims 16-22 under 35 USC 112, 1<sup>st</sup> paragraph is withdrawn in view of the arguments and Declaration provided by the applicant.

#### ***Claim Rejections Withdrawn - 35 USC § 102***

5. The rejection of claims 16 and 22 under 35 USC 102(b) is withdrawn in view of the persuasive arguments provided by the applicant.

### **NEW GROUNDS OF REJECTION**

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

6. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. Claim 34 is drawn to the administration of erythropoietin in the dose range of 750-2000 Units per kilogram. There is no support found in the specification that teaches this range for use

as an endothelial protecting amount. The specification teaches on page 12 that endothelial protecting amounts are within the range of 100-200 Units/kg, and that endothelial inhibiting amounts are within the range of 750-2000 Units/kg. Nowhere in the specification does it teach a range of 750-2000 Units/kg for endothelial protection. Application is required to remove new matter in response to this office action.

***Claim Rejections - 35 USC § 102***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Claims 16, 30-33, 35-36, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestris F *et al* (Ann Hematol. 1995 Jun;70(6):313-318). Claims are drawn to a method comprising the administration of erythropoietin to a subject, wherein the damage is caused by chemotherapeutics, and said administration of erythropoietin, administered in a dosage range of 100-200 Units/kg, is to reduce the suppression of endothelial cell growth. The claims are also drawn to a method comprising the administration of erythropoietin in conjunction with a chemotherapeutic agent, wherein the administration of chemotherapeutic is simultaneous or before the administration of the erythropoietin. Silverstris F *et al* teach a method of administering an amount of erythropoietin to subjects suffering from multiple myeloma. Silverstris *et al* also disclose that the erythropoietin is administered in the amount of 150 Units/kg. It is also taught that the erythropoietin can be administered in conjunction with chemotherapeutics, such as VMCP (a chemotherapeutic protocol which includes

Vincristine, MPH, CPM, and PSL). Silvestris *et al* describes the biological activity of the erythropoietin protein is irrelevant since the proteins is the exact same protein as applicants. Moreover, the method steps described in the prior art comprise the same steps as claimed in the instant invention, that is, the prior art teaches a method of administering erythropoietin alone or in conjunction with chemotherapeutics. And, since the product of the prior art is identical to that required by the claims, the method will inherently lead to protection of endothelial cells. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Thus, since the product of the prior art has the same chemical structure as that described in the specification, it can be assumed that the product will inherently perform the claimed process. (See MPEP 2112.02).

#### ***Claim Objections***

9. Claims 17-22, 37, and 39 are objected to because they depend from generic claims that are rejected under 35 USC 102 (b). Theses claims would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
June 30, 2003

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600